

III. Remarks

A. Status of the Application

Claims 1, 8-17 and 19 are pending herein. Claims 20 and 24 have been cancelled.

Reconsideration of this application in light of the foregoing amendments and the following remarks is respectfully requested.

B. Rejections Under 35 U.S.C. §112

Claim 20 stands rejected under 35 U.S.C. §112, first and second paragraphs. Claim 20 has been cancelled. Accordingly, the rejections of claim 20 under 35 U.S.C. §112, first and second paragraphs are moot and it is respectfully requested that they be withdrawn.

C. Rejection Under 35 U.S.C. §103(a)

Claims 1, 8-20 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,576,015 to Donzis (hereafter referred to as "Donzis '015"), U.S. Patent No. 5,531,989 to Paul (hereafter referred to as "Paul '989") and International Publication No. WO 97/05884 to Plaut (hereafter referred to as "Plaut '884"). As noted above, claims 20 and 24 have been cancelled herein. In addition, claim 18 was cancelled pursuant to a response filed on January 17, 2003. Accordingly, insofar as this rejection may be applied against claims 1, 8-17 and 19, it is respectfully traversed.

Each of claims 1, 8-17 and 19 pertain to dietary supplement compositions that include a nutritionally effective amount of β -glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides. When absorbed in combination, the effects of β -glucan, colostrum and lactoferrin on the health and well-being of the recipient are surprisingly beneficial and the combination of such compositions with citrus pectin and a complex of essential saccharides provides additional benefits as disclosed in the present application.

According to MPEP § 2142, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. In the present case, none of the criteria set forth in MPEP § 2142 have been satisfied with respect to independent claim 1 or the claims dependent thereon.

The Examiner cites Donzis '015 as disclosing that beta-glucan from yeast cell walls enhances host immune resistance to diseases caused by bacterial and viral infection. The Examiner cites Paul '989 as disclosing that a composition containing pectin, lactoferrin, and saccharides enhances the immune system. The Examiner cites Plaut '884 as disclosing that lactoferrin and colostrum strengthen the immune system.

The Examiner has taken the position that Donzis '015, Paul '989 and Plaut '884 "show that it was well known in the art at the time of the invention that all of the claimed ingredients, essential saccharides, lactoferrin, colostrum and citrus pectin, were known to enhance a patient's immune response and to treat bacterial and viral infections." The Examiner then argues that "it is well established that it is obvious to combine two or more ingredients that are known to be used for the same purpose" and, therefore, "it is obvious to combine the compositions taught by the prior art into one composition." The Examiner further argues that "it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning."

The Applicant believes the Examiner has applied an outdated and incorrect standard to support the rejection of claims 1, 8-17 and 19 over the combination of Donzis '015, Paul '989 and Plaut '884. It is submitted that the Examiner has not factually support a prima facie case of obviousness of claims 1, 8-17 and 19 based on Donzis '015, Paul '989 and Plaut '884 for the following reasons.

Donzis '015 discloses the use of beta (1,3) yeast extract glucan particles as nutritional supplements. Contrary to the claimed subject matter, however, Donzis '015 does not disclose or suggest a composition which includes beta glucan and a complex of essential saccharides.

Paul '989 discloses an immunoglobulin and fiber-containing composition for use as a dietary supplement for restoring and maintaining gastrointestinal health. Paul '989 discloses that the fiber portion of the dietary supplement may include pectin and fructo-oligosaccharides. Paul

'989 also discloses that the dietary supplement may include lactoferrin as an inhibitor of detrimental iron-catalyzed processes. Contrary to the claimed subject matter, however, Paul '989 does not disclose or suggest a composition which includes a complex of essential saccharides.

Plaut '884 discloses an infant formula which includes pasteurized milk, active lactoferrin, and an antibody which specifically binds at least one of an IgA protease and an IgA protease precursor. Contrary to the claimed subject matter, however, Plaut '884 does not disclose or suggest a composition which includes a complex of essential saccharides.

Accordingly, none of Donzis '015, Paul '989 or Plaut '884 taken alone, disclose or suggest the subject matter of any of claims 1, 8-17 and 19.

It is respectfully submitted that the combination of Donzis '015, Paul '989 and Plaut '884 is improper. According to MPEP § 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Since the Federal Circuit first addressed this issue in *ACS Hosp. Systems, Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984), the Federal Circuit has consistently held that:

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. ***Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.***

ACS Hosp. Systems, Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)); *In re Fritch*, 23 USPQ 2d 1780, 1783-1784 (Fed. Cir. 1992).

Also, the case law is clear that there must be evidence that a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. It is also clear that a rejection cannot be predicated on the mere identification of individual

components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, *with no knowledge of the claimed invention*, would have selected these components for combination in the manner claimed. *Ecolochem Inc. v. Southern California Edison*, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000). Here, no such evidence has been presented. In addition, there is absolutely no teaching, suggestion or motivation to support the combination of Donzis '015, Paul '989 and Plaut '884.

The current case law makes it clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. See *In re Dembiczak*, 50 USPQ2d, 1614, 1617 (Fed. Cir. 1999). "Combining prior art references without *evidence* of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight." *Id.* It is respectfully submitted that the only way Donzis '015, Paul '989 and Plaut '884 could be pieced together to defeat patentability is indeed to use Applicant's disclosure as a blueprint. Therefore, the combination of references is improper.

In addition, as the Federal Circuit has recognized, "*standards for the patenting of chemical entities have evolved.*" *In re Mayne*, 41 USPQ 2d 1451, 1453-54 (Fed. Cir. 1997) (emphasis added). When relying on numerous references or a modification of prior art, "*it is incumbent upon the examiner to identify* some suggestion to combine references or make the modification." *id.*

Arguably, the Examiner's reasoning for the combination of Donzis '015, Paul '989 and Plaut '884 is based upon the "obvious to try" test. In other words, if two ingredients are useful for the same purpose, then it is obvious to try to combine the ingredients. However, this is not the current standard for obviousness. As the Federal Circuit has stated:

At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known scale and corrosion prevention agents. However, *this is not the standard of 35 U.S.C. §103.*

In re Geiger, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987)(emphasis added).

The current standard for obviousness is stated below:

Our analysis begins in the text of section 103 quoted above, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the tempting but forbidden zone of hindsight, . . . when analyzing the patentability of claims pursuant to that section. Measuring a claimed invention against the standard established by section 103 requires the oft difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then accepted wisdom in the field. . . . Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. . . . In this case, the Board fell into the hindsight trap. . . . The range of sources available, however, ***does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.***

In re Dembiczak, 50 USPQ 2d 1614, 1616-17 (Fed. Cir. 1999) (quotations omitted)

It is respectfully submitted that the Examiner has not presented any evidence for the motivation which would lead one skilled in the art to combine Donzis '015, Paul '989 and Plaut '884. Making an assertion that motivation for the combination "stems from the teaching of equivalence of the ingredients in the art for the dual purposes of enhancing the immune system and treating bacterial and viral diseases" is not the clear and particular "evidence" demanded by the Federal Circuit under the current standard. Thus, under the current standard set by the Federal Circuit, the Examiner has not established a prima facie case of obviousness as to claims 1, 8-17 and 19.

The Examiner admits the use of hindsight, but justifies this impermissible use by arguing that "any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning." In support of this incorrect assertion, the Examiner cites *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) - a thirty year old case. The Applicant respectfully disagrees and argues that under the current standards, the Federal Circuit has forbidden any use of hindsight, as stated below:

This court ***forbids the use of hindsight*** in the selection of references that comprise the case of obviousness.

In re Rouffet, 47 USPQ 2d 1453, 1458 (Fed. Cir. 1998)(emphasis added).

Thus, it is respectfully submitted that the Examiner has used an outdated and impermissible standard to justify the use of hindsight.

There are hundreds of ingredients that are alleged to strengthen the immune system. To argue that the claimed combination is obvious in light of the hundreds of possible ingredients is the epitome of impermissible hindsight. Without the benefit of such hindsight, as the Examiner has admitted, the Examiner cannot maintain that the combination as claimed is obvious in light of the prior art. It is respectfully submitted that the only way Donzis '015, Paul '989 or Plaut '884 could be pieced together to defeat patentability is indeed to use Applicant's disclosure as a blueprint.

Accordingly, for the foregoing reasons, it is respectfully submitted that none of Donzis '015, Paul '989 and Plaut '884 disclose or suggest the subject matter of claims 1, 8-17 and 19. Moreover, it is respectfully submitted that it is improper to combine any of such references because there is no motivation or suggestion for such combination to achieve the Applicant's claimed dietary supplement, and even if there were, the result would not be the dietary supplement of claims 1, 8-17 and 19.

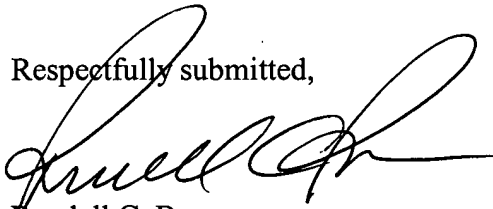
Therefore, for all of the foregoing reasons, it is requested that the rejection of claims 1, 8-17 and 19 under 35 U.S.C. §103(a) over the combination of Donzis '015, Paul '989 and Plaut '884, be withdrawn.

C. Conclusion

It is believed that all matters set forth in the Office Action have been addressed. Applicant has made a diligent effort to advance the prosecution of this application by canceling claims 20 and 24 and by submitting arguments in support of the patentability of claims 1, 8-17 and 19. In light of the foregoing amendment and remarks, Applicant submits that Claims 1, 8-17 and 19 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited. The examiner is invited to call the undersigned at the below-listed

telephone number if a telephone conference would expedite or aid the prosecution and examination of this application.

Respectfully submitted,



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